

## **REMARKS**

In the Final Office Action dated February 14, 2011, claims 1-14 were pending, all of which were rejected. Claims 1-5 and 7-11 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Reimer et al. Claims 1-14 were also rejected under 35 U.S.C. § 103(a) as allegedly obvious over Reimer et al.

This Response addresses the Examiner's rejections. Accordingly, favorable consideration of the claims as presented herein is respectfully requested.

### **Amendments to the Claims**

Applicants have herein amended claim 1. Support for the amendments to claim 1 is found in the specification at page 8, second full paragraph, for example.

After entry of this Response, claims 1-14 will be pending and under examination.

### **Claim Rejections Under 35 U.S.C. § 102(b)—Reimer et al.**

The Examiner has rejected claims 1-5 and 7-11 under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent Application Publication No. 2003/0004095 A1 ("Reimer et al.").

Specifically, the Examiner has asserted that Reimer et al. discloses the treatment of diabetes and secondary diseases by orally administering sweet whey permeate, which may be hydrolyzed, as a powder, juice, or food containing pharmaceutically acceptable additives or carriers.

Additionally, the Examiner has contended that "Reimer [et al.] specifically teaches a sweet whey protein portion included in the composition", citing paragraphs [0034] and [0047] of Reimer et al.

In response, without conceding the propriety of the Examiner's position, Applicants have herein amended claim 1, from which claims 2-5 and 7-11 depend. Applicants respectfully submit that claims 1-5 and 7-11, as presented herein, are not anticipated by Reimer et al. under 35 U.S.C. § 102(b) for at least the reasons that follow.

**Reimer et al. Does Not Disclose Compositions that Include a "Permeate"**

As an initial matter, Applicants respectfully submit that Reimer et al. does not disclose compositions that include a "permeate of ultrafiltration of a sweet whey" as the Examiner has contended. Specifically, Applicants respectfully submit that the process of ultrafiltration to obtain a permeate necessarily removes proteins and macropeptides, such as Reimer et al.'s "caseinoglycomacropeptide". In support of Applicants' position, Applicants have enclosed a copy of Sienkiewicz et al.<sup>1</sup> and a copy of a "Scheme on membrane processes"<sup>2</sup> with an Information Disclosure Statement filed herewith. Applicants respectfully direct the Examiner's attention to "Figure 110" set forth on page 331 of Sienkiewicz et al. and indicating that ultrafiltration of whey results in a permeate. Applicants also respectfully draw the Examiner's attention to the "Scheme on membrane processes" indicating that ultrafiltration separates "Proteine" (proteins) and "Makromoleküle" (other macro molecules) from the permeate. Because ultrafiltration of whey necessarily removes the "caseinoglycomacropeptide" of Reimer et al., Applicants respectfully submit that Reimer et al. does not disclose compositions that include a "permeate of ultrafiltration of a sweet whey".

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<sup>1</sup> Pages 3, 4, 11, 12, 50, 261, 262, 331, 255, 368, 371-73, and 377-78 of Sienkiewicz, T., & Riedel, C. (1990) *Whey and whey utilization*. Gelsenkirchen-Buer, Germany: Verlag Th. Mann.

<sup>2</sup> Scheme titled "Membranverfahren, Trennbereiche verschiedener Membranen" (Membrane processes, separation areas of various membranes) identifying "Proteine" (proteins) and "Makromoleküle" (other macro molecules), dated Februar[y] 2010.

**Reimer et al. Does Not Disclose the Presently-Claimed Ranges**

Applicants have herein amended claim 1, from which claims 2-5 and 7-11 depend, to recite "wherein the permeate contains 84.9% lactose  $\pm$  10%, 4.5% protein  $\pm$  10%, 0.1% fat  $\pm$  10%, 7.5% mineral substances  $\pm$  10%, the remainder being water". Applicants respectfully submit that Reimer et al. does not disclose any of ranges set forth in claim 1, as amended herein. Furthermore, Applicants respectfully submit that even Reimer et al.'s "preferred compositions", disclosed at paragraph [0034] as "compris[ing] from about 15 to about 25% protein, from about 10 to about 30% fat, and from about 40 to about 60% carbohydrate" does not suggest the recitation of claim 1, as amended herein.

Because Reimer et al. does not disclose compositions that include a "permeate of ultrafiltration of a sweet whey" and does not disclose the presently-claimed ranges, Applicants respectfully submit that Reimer et al. does not anticipate claims 1-5 and 7-11, as presented herein. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

**Claim Rejections Under 35 U.S.C. § 103(a)—Reimer et al.**

The Examiner has rejected claims 1-14 under 35 U.S.C. § 103(a) as allegedly obvious over Reimer et al. Specifically, while the Examiner has acknowledged that Reimer et al. does not teach "the composition wherein it is microencapsulated, wherein the patient is human, or wherein the permeate is hydrolyzed or partially hydrolyzed," the Examiner has asserted that it would have been obvious to one of ordinary skill in the art to encapsulate an enteral composition, to treat a human, and to use a hydrolyzed permeate.

In response, without conceding the propriety of the Examiner's position, Applicants have herein amended claim 1, from which claims 2-14 depend. Applicants respectfully submit that claims 1-14, as presented herein, are not obvious over Reimer et al. under 35 U.S.C. § 103(a) for at least the reasons that follow.

**There Was No Motivation to Change the Constituents of Reimer et al.'s Compositions**

Applicants respectfully submit that one of ordinary skill in the art would have had no motivation to change the constituents of Reimer et al.'s compositions to arrive at the presently-claimed permeate. Specifically, Applicants respectfully submit that the constituents of the presently-claimed permeate and the constituents of Reimer et al. differ substantially. For example, and as discussed above, the "preferred compositions" of Reimer et al. disclosed at paragraph [0034] have considerably more protein and fat and considerably less carbohydrate than the presently-claimed permeate. Furthermore, Applicants respectfully submit that the bovine sweet whey preparation that Reimer et al. discloses at paragraph [0104] is clearly intended for the preparation of "caseinoglycomacropeptide", not the treatment of a mammal. Additionally, Applicants respectfully submit that, unlike the presently-claimed permeate, the bovine sweet whey preparation of Reimer et al. is demineralized. Applicants respectfully submit that claim 1, as presented herein, requires a range of mineralization in sharp contrast to the bovine sweet whey preparation of Reimer et al. which is demineralized.

### **Reimer et al. Teaches Away from the Presently-Claimed Subject Matter**

Quite apart from the lack of motivation to change the constituents of Reimer et al.'s compositions to arrive at the presently-claimed permeate, Applicants respectfully submit that Reimer et al. also teaches away from the presently-claimed subject matter as a whole. Specifically, Applicants respectfully submit that Reimer et al. does not teach or disclose treating metabolic syndrome or type 2 diabetes or secondary diseases thereof by administering the presently-claimed permeate to a mammal. Applicants respectfully submit that, unlike the presently-claimed permeate, Reimer et al. in fact teaches compositions with high fat and high protein content.

### **Applicants Have Disclosed Unexpected Results**

Applicants respectfully maintain that the subject application discloses unexpected results relative to those that might have been expected in view of Reimer et al. Specifically, and as set forth in the specification at pages 10-11 and in the examples, the subject application discloses the following unexpected results:

1. A morphological correlate exists for hyperinsulinism. This means that as the  $\beta$  cell volume increases, small clusters of  $\beta$  cells appear in the exocrine pancreas,  $\beta$  cells are detected in the epithelium of the pancreas duct (indication of a neogenesis), and the  $\beta$  cell mitosis rate increases. This morphological correlation suggests an increased demand on this organ that is partially compensated by a multiplication of cells, for example, in order to utilize the excessive metabolizable energy.

2. In addition, it has been unexpectedly found according to the invention that the administration of whey permeate results in a prevention of the increase in  $\beta$  cell volume and that administration of whey permeate results in a reduction of the volume of the pancreatic islets. The administration of the pharmaceutical compositions and preparations of this invention for these purposes is therefore preferred.
3. It has been preferred according to the invention that the use of whey permeate results in a lowering of the blood lipid values, particularly in a lowering of the triglyceride concentration.
4. It has further been surprisingly found that a treatment with whey permeate resulted in a partially significant lowering of the serum insulin level when applied alone or in combination with other effective substances.
5. The results (see page 24, section entitled "Results of the oral glucose tolerance tests") particularly demonstrate a significantly improved glucose tolerance, when rats were treated with the presently-claimed permeate compared to untreated rats.

Because there was no motivation to change the constituents of Reimer et al.'s compositions, because Reimer et al. teaches away from the presently-claimed subject matter, and because Applicants have disclosed unexpected results, Applicants respectfully submit that claims

1-14, as presented herein, are not obvious over Reimer et al. under 35 U.S.C. § 103(a).

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

**Conclusion**

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'F. S. DiGiglio', with a stylized flourish at the end.

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